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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,929	01/22/2002	Julie Straub	ACU 109 CIP	7093

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,929	STRAUB ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendments. remarks, request for reconsideration filed 9/18/06. Examiner further acknowledges receipt of 1.131-declaration by Julie Straub and Howard Bernstein filed under 37 CFR 1.131 on 9/18/06. Claims 16-21 and new claim 34 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Priority

Examiner has considered the issue of 0.5 m2/mL as supported by prior filed application 09/433,486 and now US 6,395,300. However, the 0.5 m^2/ml, which is recited in claim 16, is not supported by application 09/433,486, now US 6,395,300 B1. Since applicant has antedated the Tarara reference, that prior art is no longer cited as art against the claims because the declaration under 37 CFR 1.131 antedated applicant's invention to prior to September 29, 1997.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 2001/0018072). New claim 34 is included in the rejection because Unger discloses the generic classes of drugs recited in claim 34.

Unger discloses solid porous matrix that contains bioactive agent, surfactant and solvent (abstract) and a bicarbonate (paragraph 167); the solvent can be organic or aqueous (paragraph 74); the drying methods include, lyophilizing, spray drying, and the combination thereof (paragraphs 14 and 76); some of the bioactive agents that can be prepared according to Unger are anti-neoplastic agents, methotrexate, adriamycin (paragraph 135). Surfactant is an excipient. Ammonium carbonate is a volatile pore forming salt. The instant method comprises steps a-d and the steps a-c read on mixing the bioactive agent, the volatile pore forming agent and excipient and removes the solvent by lyophilizing or spray drying. The lyophilizing step in Under is a process of removing solvent ands the pore forming agent as is claim 16 d. Unger's method steps may not specifically disclose the claimed method steps according to the steps from 16 a-d. For example, in example 1, Unger places dexamethasone in PEG and that mixture is then dissolved in methanol and rotary evaporated under vacuum. There is no demonstration that the recited method steps, in the exact order provides unexpected results to the porous matrix and also that the specific method steps are known in the art for the production of powder formulation (for example, column 2, lines 49-51; column 3, line 30 and column 9, line 41, of US 5,976,574 issued to Gordon, Nov. 02, 1999 a teaching reference discloses preparing powder by dissolving a drug in the solvent, adding excipient to the solution and then spray drying). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a porous matrix according to Unger. One having ordinary skill in the art would have

been motivated to use the known steps of preparing the powder with the expectation of forming a porous matrix. In the absence of showing factual evidence, the recited steps of making the porous matrix does not patentably distinguish the claimed invention over the prior art.

Response to Arguments

3. Applicants' arguments filed 9/18/06 have been fully considered but they are not persuasive.

Applicant argues that the therapeutic agent in Unger is suspended while it is dissolved in the instant claims and applicant states that a therapeutic agent that is only marginally soluble in a solvent will not dissolve to form a drug solution. That Unger does not disclose. That Unger discloses methylene chloride, which is a liquid and which is not volatile. That Unger does not disclose or suggest combining a volatiles solid pore-forming agent to form a porous matrix.

Response:

While Unger discloses incorporating methylene chloride as a blowing agent, it is noted that instant example 1 has methylene chloride in combination with the active agent prednisone before the homogenization and spray drying. Furthermore, the instant claims generically claims pore forming agent with the disclosure of what those pore forming agents are. The specification does not also state which agents are pore forming. Those any agent in the prior art that is disclosed as pore former and which is also disclosed by Unger would meet the recitation of a pore forming agent. In this case, it is noted that the following agents are recognized in ten art as pore forming agents, namely: *Polyethylene glycol, carbonates, glucose, amino acids, sodium*

chloride, starch, carboxymethylcellulose (see claim 9 of US 20050283229; column 9, lines 33-40 of US 5,538,733; abstract and column 2, lines 5-10 of US 5,595,762; column 7, line 64 to column 8 line 5 and claim 17 of US 5,632,727; column 8, lines 5-16 of US 5,660,849;column 9, line 55 to column 10 line 5 of US 5,681,873; and column 9, lines 41-52 of US 5,906,826).

Furthermore, Unger discloses the presence of ammonium bicarbonate, which upon spray drying would be removed and ammonium bicarbonate is one of the volatile solid pore-forming agents recited in claim 21. The comprising language of the claim is open. Unger discloses using at least methanol organic solvent as discussed above. Regarding active agent and marginal solubility as argued by applicant, it is noted that the new claim 34 set forth drugs to be selected from broad classes of drugs namely: antipyretics, antiasthmatics, anti-inflammatories, antimigraine, agents, antiarthritic agents, anticonvulsants, antibacterial agents, antiviral agents and antimicrobials some of which are marginally soluble. For example, Unger discloses anti-inflammatories such as diflunisal, ibuprofen, indomethacin, meclofenamate, mefenamic acid, naproxen, oxyphenbutazone, phenylbutazone, piroxicam, sulindac, tolmetin, aspirin and salicylates (paragraph [0135]) and indomethacin is practically insoluble. Therefore, applicant's characterization that the therapeutic agent of Unger is marginally soluble also applies to the drugs of the instant claims. Regarding solution vs. suspension, it is noted that claim 16 b is a suspension, emulsion or solution and in the same vein, the suspension of Unger meets that limitation. It is also noted that, at least Example 1 of Unger dissolves the drug with the PEG in methanol and the description states ""dissolved," which has the implication of forming a solution. Ammonium bicarbonate, a gaseous precursor in Unger beaks down to produce gaseous carbon dioxide and while the prior art may have called the carbonates as gaseous

precursors, the prior art recognizes the carbonates such as the ammonium bicarbonate as pore forming agents, *see column 9, lines 33-40 of US 5,538,733; abstract and column 2, lines 5-10 of US 5,595,762; column 7, line 64 to column 8 line 5 and claim 17 of US 5,632,727; column 8, lines 5-16 of US 5,660,849;column 9, line 55 to column 10 line 5 of US 5,681,873; and column 9, lines 41-52 of US 5,906,826).*

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 16-21 and new claim remain/is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11-14 of U.S. Patent No. 6,932,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the issued claims used the composition prepared as per

the method of the examine claims, the particle size, the TAP density and surface area in both the examined claims and the issued claims are the same.

Examiner acknowledges applicant's intention to file terminal disclaimer to overcome the obviousness type double patenting upon indication of allowable subject matter. However, the rejection will continue to be made until the rejection is overcome.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER